PLANNING GRANTS FOR NCI CANCER RESEARCH CENTERS

Release Date: November 10, 1999

PA NUMBER: PAR-00-011

National Cancer Institute

Application Receipt Date: January 14

This Program Announcement (PA) replaces PAR-97-063, which was published in the NIH Guide Volume 26, Number 18, May 30, 1997

PURPOSE:

The Cancer Centers Branch (CCB), Office of the Deputy Director for Extramural Science (ODDES), of the National Cancer Institute (NCI) invites planning grant applications for the development of Cancer Research Centers in a variety of organizational settings. The purpose is to expand the scientific, geographic and demographic diversity of the Cancer Centers Program of the NCI by encouraging research-oriented organizations to develop the qualities of a strong cancer research center and become competitive for a Cancer Center Support Grant. Cancer center planning strategies may focus on a specific research theme (e.g. diagnosis, therapy, epidemiology) or integrate a broad spectrum of research to include the basic, clinical, prevention and control, and population sciences (i.e., an NCI-designated comprehensive cancer center). All approaches to planning cancer centers are encouraged, as long as they address the six essential features of an NCI Cancer Center (i.e. cancer focus, institutional commitment, organizational capabilities, facilities, center director authority, and interdisciplinary coordination and collaboration) and as long as they take advantage of the full range of the organization's capabilities in cancer research.

This PA will expire in three years from the first receipt date. NIH Grants policies apply to these awards.

HEALTHY PEOPLE 2000:

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Planning Grants for Cancer Research Centers, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or "Healthy People 2000" Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington DC 20402-9235 (telephone 202/512-1800) or at http://odphp.osophs.dhhs.gov/pubs/hp2000.

ELIGIBILITY REQUIREMENTS:

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, and laboratories units of State and local governments, and eligible agencies of the Federal government. Applications may be from a single institution or several institutions (collaborating institutions or consortia) that do not have a Cancer Center Support Grant (CCSG), is not one of a set of collaborating institutions that make up a CCSG-supported NCI cancer center, or has not been supported by a Cancer Center Planning Grant (CCPG) or a CCSG in the last three years. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

MECHANISM OF SUPPORT:

Support for the planning and development of NCI cancer research centers will be through the National Institutes of Health (NIH) planning grant (P20) mechanism, which the NCI refers to in this PA as the Cancer Center Planning Grant (CCPG). Applicants may request up to \$175,000 in direct costs, including 3rd party Facilty and Administrative (F&A) costs. Cost-of-living increases may be requested for future years according to existing NCI policy. Applicants may request up to five (5) years of support.

Applicants will be responsible for the execution of all activities supported by this grant. Applications submitted in response to this program announcement will compete with other CCPG applications submitted during the same fiscal year. The time and amount of all CCPG awards will be contingent upon the recommendations of peer reviewers and the availability of funds. Awards will be administered under NIH grants policy as stated in the NIH Grants Policy Statement October 1998.

RESEARCH OBJECTIVES:

Background:

The Cancer Centers Program of the NCI currently supports multidisciplinary cancer research centers in a variety of institutions through the Cancer Centers Support Grant (P30) mechanism. Since the National Cancer Act of 1971, the legislative charge of the Program has been to support cancer centers that perform research in the basic, clinical, prevention and control, and population sciences; that promote and enhance multidisciplinary, interdisciplinary and translational research; and that influence how the results of research are coupled to medical practice in the communities and regions that they serve. While every cancer center does not meet all of these broad expectations (i.e. some are specialized in their research approaches), all cancer centers are organized to take maximum advantage of their research capability and opportunities in such a way that they can have an impact on reducing cancer incidence, mortality and morbidity.

Research Goals and Scope:

The strength of the NCI's Cancer Centers Program is founded in the diversity of academic, free-standing, and consortial institutions that have become NCI-supported cancer centers. The aim of this initiative is to ensure that the scientific, institutional, geographical and demographic diversity of the Program is maintained and expanded by encouraging new research-oriented organizations to apply for CCPGs and develop the research, leadership and organization capabilities expected of an NCI cancer center. The ultimate goal is to see new institutions become successful in competing for Cancer Center Support Grants and be designated as NCI cancer centers.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS:

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 20, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994 available on the web at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not94-100.html.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html

APPLICATION PROCEDURES:

Applications are to be submitted on the grant application form PHS 398 (rev. 4/98). Applications must

be received by January 14 each year. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone (301) 435-0714, email: grantsinfo@nih.gov. The title and number of the announcement must be typed in Section 2 on the face page of the application and the YES box must be marked. For those applicants with internet access, the 398 kit may be found at http://grants.nih.gov/grants/funding/phs398/forms.html.

The format for submission of a Cancer Center Planning Grant is detailed in NCI guidelines entitled, "Planning Grants for NCI-Supported Cancer Research Centers." These guidelines can be obtained from the Cancer Centers Program website at:

http://www.nci.nih.gov/cancercenters/ccb_guidelines.html. These guidelines can also be obtained from the Cancer Centers Branch of the NCI (see INQUIRIES section).

Submit a signed, typewritten original of the application, and three signed exact photocopies in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the same time of submission, please submit two additional copies of the application to:

Ms. Toby Friedberg
Division of Extramural Activities
National Cancer Institute
6116 Executive Boulevard, Room 8062, MSC 8329
Bethesda, MD 20892-8329
Rockville, MD 20852 (for express mail/courier service)

REVIEW CONSIDERATIONS:

Upon receipt, applications will be reviewed for completeness by CSR and responsiveness by the NCI. Applications will be reviewed for scientific and technical merit by an appropriate peer review group convened by Division of Extramural Activities of NCI, in accordance with the standard NIH peer review procedures. As part of the initial merit review, a process will be used by the initial review group in which applications receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed assigned a priority score, and receive a second level review by the National Cancer

Advisory Board.

The review criteria for CCPGs are outlined in the NCI guidelines entitled, "Planning Grants for NCI-Supported Cancer Research Centers". These guidelines can be obtained from the Cancer Centers Program website at: http://www.nci.nih.gov/cancercenters/ccb_guidelines.html. These guidelines can also be obtained from the Cancer Centers Branch of the NCI (see INQUIRIES section).

AWARD CRITERIA:

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review; availability of funds; and program priority.

INQUIRIES:

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquires for programatic issues to:

Margaret E. Holmes, Ph.D. Chief, Cancer Centers Branch National Cancer Institute 6116 Executive Boulevard, Suite 700 Bethesda, Maryland 20892-8345 Telephone: (301) 496-8531

FAX: (301) 402-0181 email: mh67g@nih.gov

Written and telephone inquiries about Cancer Center Planning Grants and the Cancer Centers Program in general are encouraged.

Direct inquiries regarding fiscal matters to:

Ms. Carolyn Mason Grants Administration Branch National Cancer Institute 6120 Executive Boulevard, Room 242 Bethesda, MD 20892

Telephone: (301) 496-7239

FAX: (301) 496-8601

5

email: cm113g@nih.gov

Direct inquiries regarding review issues to:

Ms. Toby Friedberg
Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Boulevard, Room 8062, MSC 8239
Bethesda, MD 20892-8239
Rockville, MD 20852 (for express mail/courier service)

AUTHORITY AND REGULATIONS:

This program is described in the Catalog of Federal and Domestic Assistance No. 93.397, Cancer Research. Awards are made under authorization of the Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro- Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

GUIDELINES

Planning Grants for NCI-supported Cancer Research Centers

1.0 Introduction:

The Cancer Centers Program of the National Cancer Institute (NCI) supports the research efforts of cancer centers throughout the nation. Since the National Cancer Act of 1971, the legislative charge of the Program has been to support cancer centers that perform research in the basic, clinical, prevention and control, and population sciences; that promote and enhance multidisciplinary, interdisciplinary and translational research; and that influence how the results of research are coupled to prevention, patient care and related practices in the communities and regions that they serve. While every NCI cancer center does not meet all of these broad Congressional expectations (i.e., the NCI encourages specialized scientific approaches), all centers are characterized by their scientific excellence and are able to take maximum advantage of their research opportunities in such a way that they can have an impact on reducing cancer incidence, mortality, and morbidity.

The strength of the NCI's Cancer Centers Program is founded in the diversity of academic, free-standing, and consortial institutions that have become NCI-supported cancer centers. The Program, in an effort to promote scientific, institutional and geographic diversity encourages all research-oriented organizations to apply for planning grants (i.e., P20s) and to develop the scientific, leadership, and organizational excellence expected of an NCI cancer center. The ultimate goal is to be successful in competing through peer review for a Cancer Center Support Grant (CCSG or P30).

Potential applicants are encouraged to read the Interim Guidelines for CCSGs, as approved by the National Cancer Advisory Board before applying for a planning grant. Any inquiries about these guidelines for planning grants and/or about the Guidelines for CCSGs are available from the Cancer Centers Program website or inquiries can be directed to the

Chief, Cancer Centers Branch
Office of Centers, Training and Resources
National Cancer Institute
6116 Executive Boulevard, Suite 700, MSC 8345
Bethesda, Maryland 20892-8345
(for Express mail use Rockville, MD 20852)

Tel: 301/496-8531 Fax: 301/402-0181 e-mail: mh67g@nih.gov

Website address: http://www.nci.nih.gov/cancercenters/

2.0 Eligibility to Apply

Any domestic for-profit or non-profit research-oriented organization or consortium of organizations may apply for a P20 grant. However, organizations that already have a Cancer Center Support Grant (i.e., P30) or already are part of a set of collaborating institutions that make up a CCSG-supported cancer center are not eligible to apply; there can be only one CCSG per institution and/or set of institutions comprising the cancer center (see Interim Guidelines for Cancer Center Support Grants). If an institution was awarded a P20 or a CCSG, it is not eligible to apply for a P20 until a minimum of three years has elapsed after the end date of the previously awarded P20 or CCSG.

3.0 Limitations and Dollar Caps on a Planning Grant Application

3.1 Time Limitation

Applicants may request up to five years of P20 support. Peer reviewers may elect to recommend shorter funding periods if they believe the planning process will require less time. However, if a five year project period is projected, there will be another peer evaluation of progress during the third year. A successful evaluation will result in five full years of funding. An unsuccessful evaluation will result in six months of phase-out support (See Section 9.0 of these Guidelines). A term will be placed on the award to this effect.

3.2 Dollar Ceiling

Applicants may request up to \$175,000 in direct costs, including 3rd party F&A costs, in the first year. Grants will be awarded for up to the peer-reviewed recommended levels and subsequent years will receive cost-of-living increases according to existing NCI policy.

4.0 General Characteristics of a Planning Effort

In planning an NCI cancer center, it is important to refer to Part I of the Guidelines for Cancer Center Support Grants, which describes the Cancer Centers Program and its policies. While the NCI expects centers to develop in a number of different organizational settings, the purpose of a cancer center is to take full advantage of the range of an institution's capabilities in cancer research.

Although the elements that an applicant emphasizes will depend on the existing state of development of the cancer center within the institution(s), especially with respect to its scientific excellence and cancer focus, in general, the planning process has a number of common characteristics in the development of all cancer centers:

- selection of a suitable planning director (or center director) who can provide both administrative and scientific leadership.

- defining the research goals and objectives of the cancer center within the scientific and organizational capabilities of the institution.
- development of an effective organizational and administrative capability within the planned center that will promote multidisciplinary research.
- identification of suitable facilities and other resources from the institution that will help the center achieve its objectives.
- identification of funded research projects and investigators at the institution that will form the initial research base of the cancer center.
- development of a suitable cancer focus for the research.
- organization of the existing funded research into highly interactive scientific "Programs" (See CCSG Guidelines) that will enhance scientific interactions and collaborations of the center investigators.
- identification of suitable scientific leadership for the center and its Programs.
- identification and establishment of shared resources important to the science of the center.
- utilization of an appropriate external advisory group to advise the planning director.
- utilization of appropriate internal planning groups.
- further development of the research base of the center and its interdisciplinary capability.
- when appropriate, the development of the appropriate linkages to patient care and community activities necessary for the conduct of clinical and population research.

5.0 Allowable Budget Items

Allowable budget items for planning and development grants may include the following:

- 1. Salaries for the planning director (or center director) and other key individuals involved in the planning process (e.g., senior scientific leaders, administrative and clerical support personnel).
- 2. Basic supply, travel costs, etc.
- 3. Internal planning activities (e.g., retreats, seminars).

- 4. External Advisors and other Consultants.
- 5. Developmental funds to be used for recruitment of new scientific staff, pilot research projects, and/or the initiation of shared resources.

No major equipment purchases or costs for alteration and renovation are allowed.

6.0 Application Procedures:

6.1 Preapplication Consultation (**Optional**)

A preapplication consultation is optional. At the request of the prospective applicant, Cancer Centers Branch staff will either arrange a formal meeting or provide assistance in other ways (e.g., conference call). Please contact the Branch Chief (See Section 1.0) for further information.

6.2 Format for the Application:

The following provides supplementary instructions to the Grant Application Form PHS 398 (rev. 4/98) for preparation of Planning Grant Applications. These forms are available at most institutional business offices, but can be provided to you upon request by Cancer Centers Branch (See Section 1.0).

In using the format below, the applicant is encouraged to **refer to the review criteria in Section 8.0.**

The format for the Planning Grant Application is as follows:

- A. **Face Page.** Instructions for the Grant Application Form PHS-398 (rev. 4/98) kit should be followed. The planning director or the center director is the principal investigator. On line 1 denote the name of the center and on line 2 denote "Program Announcement: Cancer Center Planning Grant".
- B. **Description.** Using page 2 of the PHS-398 kit, describe the objectives of the cancer center and a summary of the proposed planning activities.
- C. **Detailed Table of Contents.** A detailed table of contents with correct pagination.
- D. **Budget and Budget Justifications.** Using the budget pages provided in the PHS-398 kit, provide a detailed 12 month initial budget and future year budgets. Complete budget justifications should be provided for all individual personnel, supplies, consultant costs, etc., as requested. Reference should be made to those parts of the narrative sections that can serve to

justify the budget rather than repeating the same information in this section.

E. Biographical Sketches and Other Support

Using the instructions in the Form PHS-398 (rev. 4/98) the following should be provided:

- "Biographical Sketches" for all key individuals who will serve in leadership roles and who will provide advice and consultation from within the center and as external consultants.
- "Other Support" for all key personnel for whom a level of effort is requested on the application.

F. Narrative Descriptions:

1. The Broad Vision for The Cancer Center (**limit 2 pages**):

Describe the broad scientific objectives and goals of the cancer center; the elements to be incorporated into the center that will take advantage of the full range of research capabilities of the institution(s); the expectations for the center in facilitating and enhancing progress in cancer research; and, **as applicable**, how the center expects to use the results of research to influence improvements in patient care, prevention, outreach and education and other activities within its community and region.

2. Plans for Addressing the Six Essential Features of an NCI Cancer Center (**limit 20 pages**).

The six essential features of NCI cancer centers are: 1) a focus on cancer research, 2) organizational capabilities, 3) commitment of the parent institution(s), 4) appropriate facilities, 5) a qualified and effective center director with appropriate authority, and 6) interdisciplinary coordination and collaboration. Parts I and II of the Guidelines for CCSGs provide more detailed information about the essential features.

In preparing this section, refer to section 3. below to avoid duplicating information in the application.

3. Plans for Organizing, Strengthening and Developing the Areas of Science That Will Form the Research Base of the Cancer Center (**limit 30 pages**).

This section should assess the scientific strengths and weaknesses of the parent institution(s) based on its existing peer-reviewed research. It should provide specific strategic plans for developing the scientific capabilities of the center, especially as they relate to scientific

excellence, cancer research focus, to the formation of formal research Programs and leadership that will enhance and sustain scientific interactions and interdisciplinary collaborations, to the establishment of core resources that will facilitate and enhance the conduct of cancer research, to the recruitment of needed scientific expertise, to the use of pilot projects to promote the development of scientific excellence in cancer research, etc.

4. The Use of Internal and External Advisory Processes (limit 5 pages).

Describe the membership and responsibilities of anticipated internal and external planning groups and consultants in achieving the objectives in sections 2 and 3 above.

G. Summary of the Peer-reviewed Research Base of the Institution that can be Included In the Cancer Center.

Provide a list of all peer-reviewed research projects by principal investigator, funding organization, organization identification number, title, and project period (e.g. 5/1/99-4/30/2002)

H. Appendices.

After the application is submitted, the Scientific Review Administrator (SRA) will contact the applicant to consider appendix materials that are important to peer review. Only appendix materials approved by the SRA will used by peer reviewers

- 7.0 Application Receipt, Review, and Funding:
 - 7.1 Application Receipt Date: January 14
 - 7.2 Where to Send the Application

An original and three copies of the P20 application should be submitted to the Center for Scientific Review (CSR), NIH, according to the instructions in the Grant Application Form-398(4/98) kit. In addition, at the same time that copies are submitted to the CSR, please send two complete copies under separate cover directly to the NCI. This will greatly assist NCI staff in scheduling reviews. The NCI address is:

Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Boulevard, Suite 8062, MSC 8239
Bethesda, Maryland 20892-8239

(for express mail use Rockville, MD 20852)

Tel: 301/496-3428 Fax: 301/402-0275

7.2 Review Process, Funding and Dates

Applications will receive initial peer review at the March/April meeting of the National Cancer Institute Initial Review Group (Subcommittee A) (**NCIIRG**), and review by the National Cancer Advisory Board at the May/June meeting. The earliest possible start date for funding will be July 1.

8.0 Review Criteria:

- 8.1 The Merit of the Plans to Develop the Six Essential Features of an NCI Cancer Center.
 - 8.1.1 Focus on Cancer Research
 - 8.1.2 Commitment of the Parent Institution to Fulfilling the Objectives of the Cancer Center
 - 8.1.3 Organizational Capabilities to Conduct Cancer Research
 - 8.1.4 Appropriateness and Adequacy of Facilities
 - 8.1.5 Qualifications and Effectiveness of the Center Director with Appropriate Authority
 - 8.1.6 Interdisciplinary Coordination and Collaboration

8.2 Quality of the Science

The overall quality of the science and its potential to contribute significantly to progress in cancer research, as reflected by the existing research base of the institution(s) and the proposed plans to enhance its research capabilities.

8.3 Special Qualities of the Cancer Center

Any special qualities or strengths of the planned cancer center that will contribute significantly to the scientific, demographic, and/or geographic diversity of the NCI Cancer Centers Program.

8.4 Overall Merit of the Planned Cancer Center

The overall merit as based on 8.1, 8.2, and 8.3 above **and** the potential of the center to become competitive for a Cancer Center Support Grant within in the time frame of the proposed planning period.

9.0 Progress Peer Review

If a planning grant application is approved and funded for a five year period, the NCI will conduct a peer review of progress by the **NCIIRG** during the third year. The **NCIIRG** will have the option of recommending that the planning effort be continued for an additional two years based on satisfactory progress in developing the center **or** of recommending six months phase-out support based on a lack of significant progress. Peer reviewers will be asked to evaluate how the planning center has progressed based on the Summary Statement of their original competing application. Specifically, reviewers will be asked to evaluate how well the planning center has achieved its own stated objectives and responded to initial peer review concerns.